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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,712	03/19/2004	John S. Fisher	1139.20.DIV3	2711

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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/708,712	FISHER, JOHN S.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of an earlier filing date under 35 U.S.C. 120 appears to erroneously cite the wrong patent number for a parent application of the instant application. Specifically, Applicant states that the present application is a divisional application of U.S. Serial No. 10/065,155 *which is a continuation-in-part of U.S. Patent No. 6,592,608 that issued on July 15, 2003.* However, U.S. Serial No. 10/065,155 recites that application is a continuation-in-part of U.S. Serial No. 09/682,252, filed on August 9, 2001, which is now abandoned. U.S. Serial No. 09/683,282, which matured into U.S. Patent No. 6,592,608, is drawn to a bioabsorbable sealant that appears unrelated to the instant invention.

In view of the foregoing, Paragraph [0002] of the specification of the present application should be amended to reflect the appropriate parent application number for which the benefit of an earlier filing date under 35 U.S.C. 120 is claimed. Furthermore, said paragraph should be updated to include the current status of all the parent application cited therein.

The Application Data Sheet filed March 19, 2004 also cites the wrong application serial number and patent number under the Continuing Data section. An application data sheet identifying this application by application number and filing date, and correcting the erroneous continuity data citation is required.

Specification

2. The disclosure is objected to because of the following informalities:

a. In paragraph [0008], line 17, --slides-- apparently should be inserted following "on".

b. In paragraph [0028], line 5, "if" apparently should read --of--.

Appropriate correction is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 1 is objected to because of the following informalities: in lines 30, 32-34, 36 and 39, "means" apparently should be deleted. Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,709,408 (Fisher) in view of U.S. Patent No. 4,693,257 to Markham.

The Fisher patent claims an aspiration biopsy needle for scraping cellular material from tissue. The needle meets all of the structural limitations recited in the providing, forming and communicating steps of claim 1 of the instant application. Particularly, claim 1 of the Fisher patent recites an aspiration biopsy needle of elongate, hollow construction with a uniform diameter along an extent of the needle; an open, beveled distal end forming a first sharp edge for scraping cellular material when the needle is inserted into tissue by proximal-to-distal movement; an angled slot formed in the needle near the distal end including a second sharp edge for scraping tissue of a cellular size as the needle is displaced in a distal-to-proximal movement; and a means for communicating a vacuum to a proximal end of the needle to draw the scraped cellular material into the interior of a needle. Claim 1 of the Fisher patent also provides functional language in the "whereby" clause at the end of the claim that corresponds to the depositing, staining, and subjecting to microscopic inspection steps of claim 1 of the instant application. Therefore, claim 1 of the Fisher patent teaches all of the limitations of the method of claim 1 of the instant application except for the steps of providing a syringe, an endoscope and a guide tube; positioning the guide tube in the endoscope; securing the FNA biopsy needle to the distal end of the guide tube; positioning the biopsy needle in operative relation to a lesion; and

retracting the guide tube and hence the needle so that cellular material is scraped from the lesion as the needle is pulled from the lesion.

The Markham patent teaches a conventional method for using a needle aspiration biopsy device. The aspiration biopsy needle **24** is positioned on and secured to the distal end of a guide tube **23** that has a syringe **25** fixed to a proximal end thereof. The guide tube is inserted into the operation channel of an endoscope; the guide tube **23** is advanced to position the biopsy needle in operative relation to a lesion; the syringe applies a vacuum to the needle and the needle shaves off tissue; and finally, the guide tube and hence the needle are retracted into the endoscope (col. 2, lines 40-58).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that by mounting a FNA biopsy needle having the structure of claim 1 of the Fisher patent on a conventional guide tube and operating said aspiration biopsy needle in a conventional fashion as taught by the Markham patent, the structure of the Fisher needle would inherently scrape tissue from the lesion as the guide tube is retracted as required by claim 1 of instant application. Since conventional operation, similar to that taught by Markham, of a biopsy needle of the Fisher patent would inherently require the method steps of claim 1 of the instant application, claim 1 of the Fisher patent and claim 1 of the instant application are not patentably distinct.

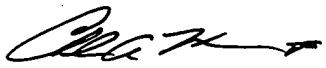
Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vijfvinkel ('111) teaches a surgical instrument for removing tissue. Ouchi ('132) teaches an endoscopic tissue collecting instrument.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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June 24, 2004